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09/975,273	10/12/2001	Harry Yu	004814.00003	8862

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EXAMINER

FORD, ALLISON M

ART UNIT PAPER NUMBER

1651

DATE MAILED: 09/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/975,273

Applicant(s)

YU ET AL.

Examiner

Allison M Ford

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/6/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 7-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Invention VIII in the reply filed on 7/21/04 is acknowledged.

Status of Application

Claims 5-6 are being examined for patentability. Claims 1-34 are pending in the current application, of which claims 1-4 and 7-34 have been withdrawn from consideration.

Priority

Acknowledgement is made of applicant's claim to provisional application number 60/239,259, filed Oct. 12, 2000 under 35 U.S.C. 119(e).

Information Disclosure Statement

The information disclosure statement submitted by the applicant does not provide proper listing of the non-patent literature which was submitted by applicant. In order to ensure the non-patent literature will be considered a proper information disclosure including all pertinent patents, foreign patent, and non-patent literature must be provided, as required by 37 CFR §§ 1.97 and 1.98.

Specification

The abstract of the disclosure is objected to because it contains incorrect information. Page 1 of the specification defines a spherical microcapsule to have a high surface-to-volume ratio; this is incorrect. A sphere has a low surface-to-volume ratio, volume of a sphere = $\frac{4}{3}\pi r^3$, surface area of a sphere = $4\pi r^2$. Correction is required. See MPEP § 608.01(b).

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The abstract of the disclosure is further objected to because it contains unclear scientific notation: mol% (See pg. 8-9). Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a macro-porous skeleton comprising chitosan at a concentration of 0.01-0.02% (w/v), does not reasonably provide enablement for any concentration (w/v). Chia et al (Biomaterials, 2002) teaches chitosan can form a macro-porous exoskeleton only when used in the range of 0.01-0.02% (w/v); any less does not permit sufficient coverage of the microcapsule surface, any more causes disintegration of inner matrix upon contact (See pg. 7). The claim does not accurately teach the required limitations necessary to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Applicant's claim 5 is directed to a microcapsule comprising an inner extracellular matrix and an outer shell surrounding and supporting the extracellular matrix; wherein said microcapsule is permeable to nutrients necessary to sustain normal metabolic functions of the cells and to toxins released by the cells; and wherein said outer shell comprises a macro-porous exoskeleton formed by complex coacervation with said extracellular matrix.

It is unclear what comprises the inner extracellular matrix, as the components of the matrix are not defined in the claim. It appears applicant is intending to claim what is described in the specification as a Type-III microcapsule, which comprises a Type-I microcapsule re-suspended in an exoskeleton (See specification, pg 6). If applicant intends for the claimed microcapsule to comprise all the features of a Type-III microcapsule, the structural limitations must be addressed and presented in the current claim, including the biopolymer and biocompatible synthetic polyelectrolyte layers which form the inner cellular matrix, their respective charges, charge densities, molecular weights, and in what capacity the charges permit it to form complex coacervation with the exoskeleton.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5 & 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Baetge et al, in light of Koster ("The Integrin Page").

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Applicant's claim 5 is drawn to a microcapsule comprising an inner extracellular matrix and an outer shell surrounding and supporting the extracellular matrix; wherein said microcapsule is permeable to nutrients necessary to sustain normal metabolic functions of the cells and to toxins released by the cells; and wherein said outer shell comprises a macro-porous exoskeleton formed by complex coacervation with said extracellular matrix. Claim 6 requires the exoskeleton to further comprise at least one of alumina, alumina sol, and chitosan.

Baetge et al teach a biocompatible capsule (which applicant refers to as a microcapsule) comprising a core of cells immobilized within an extracellular matrix, and an outer jacket surrounding the inner extracellular matrix (which applicant refers to as an outer shell or exoskeleton) (See col. 10, ln 66- col. 11, ln 6). The capsule's matrices are permeable to nutrients and biological molecules by means of macropores (See abstract; col. 4, ln 34-39; col. 13, ln 7-8; and col. 13, ln 60-65) (Claim 5).

Baetge et al further teach encapsulating a core of cells within a porous biocompatible capsule (which applicant refers to as a microcapsule) comprising chitosan (See col. 10, ln 66-67 and col. 11, ln 38-42). The capsule is permeable to nutrients and biological molecules by means of macropores (See abstract; col. 4, ln 34-39; col. 13, ln 7-8; and col. 13, ln 60-65). The encapsulated cells can secrete proteins that comprise the extracellular matrix, such as collagen, fibronectin, and laminin (See Koster). Therefore Baetge et al teach a microcapsule that contains cells capable of secreting proteins to form an inner extracellular matrix, surrounded by a porous outer shell, comprising chitosan (Claim 6). Therefore the reference anticipates the claimed subject matter.

Claims 5 & 6 are rejected under 35 U.S.C. 102(b) as being unpatentable over Torobin (US Patent 4,743,545), in light of Koster ("The Integrin Page").

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Applicant's claim 5 is drawn to a microcapsule comprising an inner extracellular matrix and an outer shell surrounding and supporting the extracellular matrix; wherein said microcapsule is permeable to nutrients necessary to sustain normal metabolic functions of the cells and to toxins released by the cells; and wherein said outer shell comprises a macro-porous exoskeleton formed by complex coacervation with said extracellular matrix. Claim 6 requires the exoskeleton to comprises at least one of alumina, alumina sol, and chitosan.

Torobin teaches encapsulating cells within a porous microsphere comprising alumina (which applicant refers to as a microcapsule) (See col. 4, ln 9-26; col. 5, ln 38-58; col. 13, ln 1-9; and col. 13, ln 28-43). The microsphere is permeable to nutrients and toxins as well as biological products of the cells (See col. 5, ln 38-58).

The encapsulated cells can the secrete proteins that comprise the extracellular matrix, such as collagen, fibronectin, and laminin (See Koster); thus the cells can produce an extracellular matrix.

Therefore Torobin teaches a microcapsule that contains cells capable of secreting proteins to form an inner extracellular matrix, surrounded by a porous outer shell, comprising alumina (Claims 5 & 6). Therefore the reference anticipates the claimed subject matter.

Conclusion

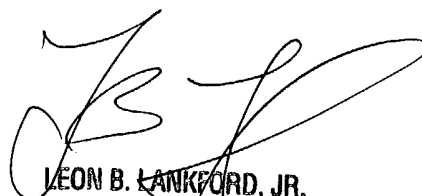
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M Ford whose telephone number is 571-272-2936. The examiner can normally be reached on M-F 7:30-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0927. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford
Examiner
Art Unit 1651



LEON B. LANKFORD, JR.
PRIMARY EXAMINER